

# EXHIBIT J

1                   IN THE UNITED STATES DISTRICT COURT  
2                   FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA  
3                   CHARLESTON DIVISION

4                   -----  
5                   IN RE ETHICON, INC., PELVIC       :Master File NO.  
6                   REPAIR SYSTEM PRODUCTS       :2:21-MD-02327  
7                   LIABILITY LITIGATION       :  
8                   :MDL 2327

9                   THIS DOCUMENT RELATES TO THE       :  
10                  FOLLOWING CASE IN WAVE 2 OF       :  
11                  MDL 200                        :  
12                  -----

13                  PAMELA BAILEY AND               :  
14                  HOUSTON BAILEY,                :  
15   :JOSEPH R. GOODWIN  
16                  Plaintiffs,                    :U.S. DISTRICT JUDGE  
17                  v.                               :  
18                  ETHICON, INC., et al.,        :  
19   :Case No.  
20                  Defendants.                     :2:12-CV-01700  
21                  -----

22   June 6, 2016

23   Videotaped deposition of  
24   KONSTANTIN WALMSLEY, M.D., held at COURTYARD  
MARRIOTT WEST ORANGE, 8 Rooney Circle, West  
Orange, New Jersey, before Margaret M. Reihl,  
RPR, CCR, CRR, CLR and Notary Public, on the  
above date, commencing at 10:59 a.m.

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Konstantin Walmsley, M.D.

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I N D E X

|                           |       |
|---------------------------|-------|
| WITNESS:                  | Page  |
| KONSTANTIN WALMSLEY, M.D. |       |
| By Mr. Griffin            | 4, 64 |
| By Mr. Thompson           | 61    |

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E X H I B I T S

|  |        |
|--|--------|
| WALMSLEY-BAILEY DEPOSITION EXHIBITS                          | MARKED |
| No. 1 Notice of Deposition of<br>Konstantin Walmsley, M.D.   | 4      |
| No. 2 Rule 26 Expert Report of<br>Konstantin Walmsley, M.D.  | 6      |
| No. 3 IME exam notes of Dr. Walmsley<br>date of exam: 5/3/16 | 6      |
| No. 4 Exam notes of Dr. Osterloh<br>date of exam: 6/28/11    | 19     |

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1                   ... KONSTANTIN WALMSLEY, M.D., having  
2                   been duly sworn as a witness, was examined and  
3                   testified as follows ...

4   BY MR. GRIFFIN:

5               Q.     Dr. Walmsley, my name is Will Griffin.  
6   I represent Johnson & Johnson, and I'm here to ask you  
7   questions regarding Pamela Bailey.

8                   Have you been hired in a case styled  
9   Pamela Bailey versus Ethicon to testify on behalf of  
10   Pamela Bailey?

11              A.     I have.

12              Q.     Okay. Could you give us your full name.

13              A.     Konstantin Walmsley.

14              Q.     And, Dr. Walmsley, where do you  
15   practice?

16              A.     New Jersey.

17              Q.     And you've been kind enough to tell me  
18   during an earlier deposition, you are a urologist,  
19   correct?

20              A.     Yes, sir.

21                   (Document marked for identification as  
22   Walmsley-Bailey Deposition Exhibit No. 1.)

23   BY MR. GRIFFIN:

24              Q.     I'm going to show you what's marked as

1 Exhibit 1 to your deposition in this case, which is a  
2 Notice of Deposition.

3 Were you provided that?

4 A. I was.

5 Q. Did you bring the documents that were  
6 requested in that Notice of Deposition?

7 A. I have them, the majority of them  
8 electronically with me today.

9 Q. But have you brought me a thumb drive or  
10 anything like that?

11 A. I have not.

12 Q. Okay. Have you brought any of them in  
13 paper form?

14 A. I have not.

15 Q. Okay. And the only thing -- as I  
16 understand it, the only thing you have brought with you  
17 is your report that's in paper form; is that true?

18 A. In paper form, this is true, yes.

19 Q. Have you even brought your examination  
20 notes?

21 A. I have them electronically.

22 Q. Okay.

23 MR. GRIFFIN: We'll mark this as

24 Exhibit 2.

1 (Document marked for identification as  
2 Walmsley-Bailey Deposition Exhibit No. 2.)

3 BY MR. GRIFFIN:

4 Q. I'm going to show you what was marked as  
5 Exhibit 2 and make sure I haven't drawn all over it.

6 I'm going to show you what's marked as  
7 Exhibit 2. Could you identify that?

8 A. Yes. This is a Rule 26 expert report on  
9 Pamela Bailey.

10 Q. Did you -- is that your report?

11 A. Yes, sir.

12 Q. Did you draft it?

13 A. I did.

14 (Document marked for identification as  
15 Walmsley-Bailey Deposition Exhibit No. 3.)

16 BY MR. GRIFFIN:

17 Q. Okay. I'm going to show you Exhibit 3  
18 and ask if you can identify that?

19 A. This is my independent medical  
20 examination of Pamela Bailey dated May 3rd, 2016.

21 Q. Okay. Dr. Walmsley your report  
22 indicates the various medical records you reviewed.  
23 Did you review any depositions?

24 A. Yes, I did.

1 Q. What depositions?

2 A. I believe I reviewed the deposition --  
3 not believe -- I reviewed the deposition of Dr. Adam  
4 and Ms. Bailey.

5 Q. Did you review Dr. Perlow's deposition?

6 A. I don't recall reviewing Dr. Perlow's  
7 deposition. It may have been sent to me. I don't  
8 believe I had the time to review it.

9 Q. So, as we sit here today, you do not  
10 have any knowledge of what Dr. Perlow did know or did  
11 not know regarding risks and complications of pelvic  
12 mesh procedures?

13 A. I do not.

14 Q. So you do not intend to offer an opinion  
15 that Dr. Perlow was unaware of the potential risk and  
16 complications of the TVT procedure, true?

17 A. The only shortcoming, once again, to his  
18 informed consent was based on his knowledge or lack  
19 thereof based on the IFU.

20 Q. But an IFU doesn't include all the  
21 risks -- your opinion is that the IFU doesn't include  
22 all the risks that would allow a doctor to give  
23 adequate informed consent?

24 A. Yes, this report speaks to that.



1 Q. Okay. And I guess the basis of that is  
2 that a physician has to know of the potential risks and  
3 complications to give an adequate informed consent,  
4 correct?

5 A. That's correct.

6 Q. And you would agree physicians may  
7 become aware of risk and complications of a TVT  
8 procedure by means other than an IFU, true?

9 A. This is in part true.

10 Q. They might obtain it from their  
11 training, true?

12 A. Yes.

13 Q. Experience, true?

14 A. Yes.

15 Q. Literature, true?

16 A. Correct.

17 Q. Colleagues?

18 A. Yes.

19 Q. Seminars?

20 A. True.

21 Q. And from what I understand from your  
22 earlier answers, you have no knowledge of what  
23 Dr. Perlow had obtained in terms of knowledge from his  
24 training, experience, literature, discussions with

1 colleagues, seminars, things of that sort, correct?

2 A. Not from my evaluation of the medical  
3 records, no.

4 Q. And so, as we sit here today, you are  
5 not offering an opinion that Dr. Perlow did not have  
6 sufficient knowledge of the risk and complications of  
7 the TVT procedures to advise the patient, correct?

8 MR. THOMPSON: Object to the form.

9 THE WITNESS: I am offering that  
10 opinion.

11 BY MR. GRIFFIN:

12 Q. And you are offering that opinion  
13 despite the fact that you have absolutely no knowledge  
14 of what information Dr. Perlow had in his possession at  
15 the time of the surgery of Ms. Bailey that he may have  
16 obtained from his training, experience, literature,  
17 discussions with colleagues and seminars, correct?

18 A. Well, I do have knowledge of one of the  
19 elements required from the informed consent that  
20 Dr. Perlow had at the time of that surgery.

21 Q. That was the IFU?

22 A. That's correct.

23 Q. But that wasn't my question.

24 You have absolutely no knowledge of what

1 information Dr. Perlow had in his possession at the  
2 time of the surgery of Ms. Bailey that he may have  
3 obtained from his training, experience, literature,  
4 discussions with colleagues and seminars, correct?

5 A. Well, I would disagree with that  
6 comment.

7 Q. Did you read his deposition to attempt  
8 to obtain that knowledge?

9 A. I have not read his deposition.

10 Q. So you do not know what Dr. Perlow knew  
11 or didn't know at the time of Ms. Bailey's procedure,  
12 true?

13 A. I'm not aware of what he shared in his  
14 deposition regarding what he knew or didn't know.

15 Q. And if you're not aware of that, then  
16 you don't know what he knew in terms of risk and  
17 complications at the time of the surgery of Ms. Bailey,  
18 correct?

19 A. That's not entirely true, but in part  
20 true.

21 Q. Well, the only thing that you're aware  
22 of is the IFU, and you don't even know whether he  
23 reviewed the IFU before he performed this procedure,  
24 true?

1           A.       I would assume he would have reviewed  
2   it, but it's possible he did not review it.

3           Q.       So the answer is you don't know, true?

4           A.       I don't know if he reviewed the IFU.

5           Q.       Do you know whether Dr. Perlow addressed  
6   the issue of whether additional information in the IFU  
7   would have changed his mind in recommending the  
8   procedure?

9           A.       I'm not aware of that.

10          Q.       In your -- you have a Case Specific  
11   Opinion 1. Let me ask you this, let me go to your  
12   General Opinion 2 since it's in this report.

13          A.       Sure.

14          Q.       You do agree that there are risks of  
15   dyspareunia with your autologous fascial slings,  
16   correct?

17          A.       Yes.

18          Q.       So even the, quote, safer alternative  
19   designs that you say existed in 2001 carried the risk  
20   of dyspareunia, true?

21          A.       Yes.

22          Q.       And there's no way for you to predict in  
23   advance which particular patient may have dyspareunia  
24   and which may not, correct?

1 A. Not entirely true.

2 Q. What?

3 A. Not entirely true.

4 Q. Fill me in.

5 A. Well, I mean, if patients have  
6 conditions that might otherwise increase their risk of  
7 dyspareunia, you can sometimes counsel patients that  
8 they might have a higher risk of dyspareunia because of  
9 prior surgery, et cetera.

10 Q. I get what you're saying, but the point  
11 is you don't know which patients are going to develop  
12 dyspareunia and which patients are not, correct?

13 A. Not with 100% accuracy, no.

14 Q. Have you had patients develop  
15 dyspareunia?

16 A. After surgery you mean?

17 Q. Yes.

18 A. I have.

19 Q. In what kind of procedures?

20 A. Certainly after sling surgery.

21 Q. Autologous?

22 A. Rarely, but yes.

23 Q. So the autologous fascial slings, you  
24 have personal experience with patients who have

1 developed dyspareunia, correct?

2 A. I have.

3 Q. And you have had patients with mesh  
4 procedures who have developed dyspareunia as well,  
5 correct?

6 A. That's correct.

7 Q. As I understand it, you do not use the  
8 Ethicon products, though, correct?

9 A. Not in my private practice.

10 Q. You use the Bard Coloplast and AMS  
11 devices?

12 A. The answer to that is yes.

13 Q. And using those devices you have had  
14 patients develop dyspareunia as well?

15 A. I have.

16 Q. Your Case Specific Opinion Number 1 in  
17 the Bailey case, you indicate that recognized causes of  
18 sling erosion include and number one is surgical error  
19 in implantation technique; is that correct?

20 A. Yes.

21 Q. And what would the surgical error be?  
22 Would that be making it taut rather than tension free?

23 A. That might be one of the ways.

24 Q. So if the surgeon made the TVT sling

1 taut rather than leaving it tension free, that would  
2 be -- cause the potential for vaginal sling erosion?

3 A. That could happen.

4 Q. Do you know what Dr. Perlow's  
5 complication rate was in terms of over tensioning these  
6 devices?

7 A. I'm not aware of that.

8 Q. What is the complication rate for over  
9 tensioning a TVT?

10 A. Well, it depends on where you're trying  
11 to extract that information, so it's very hard to  
12 answer that question with much accuracy.

13 Q. What's your understanding, generally?

14 A. Probably on the order of single digit  
15 percentage points.

16 Q. Something less than 10%?

17 A. Yeah, I would conjecture that's about  
18 right.

19 Q. If a physician is having double that,  
20 then the physician may have -- may be having a problem  
21 with figuring out how to implant the device, correct?

22 A. Possibly.

23 Q. Well, not just possibly, more likely  
24 than not, correct?

1 MR. THOMPSON: Object to the form.

2 THE WITNESS: To some degree, you know,  
3 the variable could also be patients as well and  
4 also might also be related to how one defines  
5 over tensioning.

6 BY MR. GRIFFIN:

7 Q. What would it tell you if Dr. Perlow  
8 testified that he had a problem with over tensioning  
9 these devices?

10 A. That would tell me that perhaps he had a  
11 learning curve.

12 Q. If you're over tensioning the device,  
13 you're pulling it taut, correct?

14 A. Possibly.

15 Q. What you want to do is leave it tension  
16 free, correct?

17 A. That's the goal of the procedure, yes.

18 Q. Did you make a determination as to  
19 whether Dr. Perlow did, I guess, over tension the  
20 device?

21 A. I did formulate an opinion regarding  
22 that.

23 Q. So you have the Case Specific Opinion  
24 Number 1 that there was vaginal sling erosion which was



1 caused by shrinkage of the mesh, true?

2 A. Retraction and shrinkage of the mesh.

3 Q. Right. And in coming to that opinion,  
4 you ruled out surgical error on implantation, correct?

5 A. Correct.

6 Q. And the way you ruled that out was how?

7 A. Dr. Perlow's operative dictation and  
8 Mrs. Bailey's postoperative treatment course.

9 Q. So there's two things there, one would  
10 be his operative report?

11 A. Correct.

12 Q. And in the operative report it indicates  
13 he left it tension free, true?

14 A. Yes.

15 Q. In other words, he didn't pull it taut,  
16 correct?

17 A. He specifically used a spacer, a pair of  
18 scissors as a spacer to ensure tension-free placement.

19 Q. And if you do that, you're not going to  
20 pull it taut, right?

21 A. Should not.

22 Q. And if you're pulling the sling taut,  
23 you run the risk of over tensioning the device,  
24 correct?

1           A.       That may be one reason to do that -- or  
2       one way to do that.

3           Q.       And your understanding was that  
4       Dr. Perlow did not do that, correct?

5           A.       In the setting of using a spacer, such  
6       as a Metzenbaum scissors, it's hard even in the setting  
7       of a taut pull to set it too tight.

8           Q.       I'm going to show you Bailey WellStar  
9       Windy Hill Hospital, Page 7 of the MDR.

10                   Does Dr. Perlow indicate that the  
11       vaginal tape was pulled tight, that it was taut, so  
12       that it would suspend the urethra?

13           A.       It states, vaginal tape was pulled taut  
14       so that it would suspend the urethra, and Metzenbaum  
15       scissors was used as a spacer.

16           Q.       That's not what you would expect to find  
17       in operative dictation for placement of a TVT, correct?

18           A.       Possibly, but not necessarily.

19           Q.       You've never seen a physician indicate  
20       that they pulled it taut, have you?

21           A.       I don't know if I would say that  
22       necessarily.

23           Q.       Can you remember a single case you've  
24       reviewed or where you, yourself have done it where

1     you've used the words pulled the TVT or the similar  
2     device taut?

3             A.       Well, when one is setting a TVT sling,  
4     you're removing spacers, plastic sheaths that are  
5     around the sling. Oftentimes there is a tendency when  
6     removing those sleeves to create some tension.  
7     However, if you have a spacer in place, that more or  
8     less protects that pulling of sheath out phenomenon  
9     from over tensioning.

10            So even though his operative note  
11    memorialized a taut pull of the sling, the presence of  
12    the scissors as a spacer should ensure a tension-free  
13    placement.

14            Q.       Doctor, if he says he pulled it taut in  
15    the operative report and he indicated he had a 20%  
16    complication rate of over tensioning these devices,  
17    does that tell you that there's the potential in this  
18    particular case, Pamela Bailey's case, that the TVT was  
19    initially over tensioned?

20            MR. THOMPSON:   Object to the form.

21            THE WITNESS:    I would disagree with  
22            that.

23    BY MR. GRIFFIN:

24            Q.       And is that because of your finding that

1 she did not indicate any problems of emptying her  
2 bladder initially after the surgery?

3 A. Correct.

4 Q. That would be the only reason, correct?

5 A. That would be my main reason.

6 Q. You can't think of any other reason, as  
7 we sit here, true?

8 A. Well, the only other reason would be the  
9 use of a spacer.

10 Q. If she did have symptoms of trouble  
11 emptying her bladder from the time of the surgery, that  
12 would be indicative of the sling being placed too  
13 tightly, correct?

14 A. Not necessary.

15 Q. Didn't you just tell me that?

16 A. Well, it depends on the chronology with  
17 which her obstructive symptoms presented.

18 Q. Okay. If she had the symptoms of  
19 inability to empty her bladder from the time of the  
20 surgery itself, that would be indicative that the sling  
21 was possibly placed too tightly, correct?

22 A. That would be a possibility.

23 (Document marked for identification as  
24 Walmsley-Bailey Deposition Exhibit No. 4.)

1 BY MR. GRIFFIN:

2 Q. Let me show you Exhibit 4 and ask you if  
3 she told Dr. Osterloh that she had had trouble emptying  
4 her bladder from the time of her surgery?

5 A. That's what's stated on this note.

6 Q. And if that is, in fact, true, that is a  
7 potential sign that the midurethral sling placed by  
8 Dr. Perlow was placed too tight or in a nontension free  
9 manner, correct?

10 A. Once again, I would disagree with that  
11 strictly on the basis of a sling in my practice that's  
12 been over tensioned too tightly will literally present  
13 with retention almost immediately to the point that a  
14 patient requires catheterization to empty her bladder.

15 One thing that can happen following  
16 sling surgery, even if it's placed in a tension-free  
17 fashion, is that patients can suffer symptoms of  
18 incomplete emptying that are more related on swelling  
19 and inflammation post sling implantation that then can  
20 resolve over time. The other possibility is that a  
21 sling that's placed in a tension-free fashion can,  
22 through the formation of scar plate or contraction,  
23 develop an obstructive symptomatology.

24 So the presence of a note ten years

1 after the sling that speaks to that raises the  
2 possibility, of course, but doesn't necessarily rule  
3 that in with the highest degree of certainty, only  
4 insofar as this patient did not require catheter or  
5 catheterization following her surgery.

6 Q. So it raises the possibility -- the  
7 patient's statement that she had trouble emptying her  
8 bladder after her TVT procedure raises the possibility  
9 that the device was placed too tautly; is that correct?

10 MR. THOMPSON: Object to the form.

11 THE WITNESS: I'm not offering that  
12 opinion, only because if that were the case,  
13 she would literally require a catheter to drain  
14 her bladder. That's typically the complication  
15 of over tensioning is urinary retention  
16 requiring a catheter, that in 2016, for  
17 example, typically requires -- the standard of  
18 care calls for a revision of the sling within a  
19 few weeks because of that phenomenon.

20 So maybe I'm defining over tensioning in  
21 a different way. Obviously, the sling did  
22 ultimately become too tight because of the  
23 findings discovered later on. That being said,  
24 the fact that there's the description of taut

1 in an operative dictation to me is put in the  
2 proper context of a spacer being used doesn't  
3 suggest over tensioning.

4 Q. Okay. The one possibility for a patient  
5 experiencing the inability to completely void or empty  
6 the bladder is the fact that a TVT may have been placed  
7 in too tight a manner, correct?

8 A. Depending upon the chronology with which  
9 you're posing that question, that's possible.

10 Q. Okay. Not every TVT that is placed too  
11 tightly requires the placement of a catheter, correct?

12 A. That would be incorrect.

13 Q. Are you saying every TVT that is placed  
14 too tightly requires the use of a catheter?

15 A. Almost invariably, yes.

16 Q. Some patients simply have the inability  
17 to void or feel like they have completely voided, true?

18 A. Not true to my -- no, I would disagree  
19 with that.

20 Q. You don't have that understanding based  
21 on the literature you've reviewed, correct?

22 A. Based on the literature that I reviewed  
23 and my own clinical experience, over tensioning of the  
24 sling is a phenomenon that presents with the immediate

1 need for a catheter, a catheter to drain one's bladder  
2 and sometimes can be related to a voiding dysfunction  
3 that you see immediately following surgery as well.

4 Q. You indicate that there was mesh  
5 erosion, not mesh exposure. Do you make a distinction  
6 between those two terms?

7 A. I think of them along a continuum.

8 Q. Okay.

9 A. In other words, first off, an erosion  
10 event can include eroding into spaces or organs other  
11 than the vagina. Whereas an extrusion event really is  
12 an erosive event into the vaginal space. I think of an  
13 extrusion as a mini vaginal erosion. That's how I  
14 would define it, an exposure being another means of  
15 defining an erosion of mesh into the vaginal space. So  
16 I guess extrusion and exposure are subsets of an  
17 erosion condition.

18 Q. Did you read Dr. Adam's testimony on  
19 that?

20 A. I did.

21 Q. Okay. Did Dr. Adam remove the mesh in  
22 this particular case?

23 A. Partial mesh removal.

24 Q. Did he find evidence of degradation of



1 the mesh?

2 A. I don't recall seeing that.

3 Q. You don't recall seeing that, or did he  
4 not find that?

5 A. I don't recall him mentioning that he  
6 found that.

7 Q. You know he was asked that specifically,  
8 true?

9 A. He was.

10 Q. And he said he did not see that, true?

11 A. Well, that's -- yes.

12 Q. I just want to make sure you're not  
13 recalling it versus --

14 A. That's fair.

15 Q. That's what he said?

16 A. Yeah.

17 Q. You would agree that Dr. Adam did not  
18 find evidence of degradation, curling, fraying or  
19 roping of the mesh when he took out a portion of the  
20 mesh, true?

21 A. This is true.

22 Q. You make the statement or you give the  
23 opinion that Dr. Perlow placed it tension free,  
24 correct?

1 A. That's correct.

2 Q. You have no way of knowing, in fact,  
3 whether he did or didn't, other than the statement that  
4 he used the Metzenbaum scissors and your belief that  
5 she would have needed to be catheterized, correct?

6 A. I believe I also have a way of knowing  
7 in light of my having performed an IME on this patient  
8 as well.

9 Q. Before we get to the IME, you made the  
10 statement that the mesh was placed tension free without  
11 reading the deposition of Dr. Perlow, true?

12 A. That's correct.

13 Q. And when you made the statement, in your  
14 opinion, which I think is Exhibit 2; is that right?

15 A. Yes, sir.

16 Q. You were unaware of what Dr. Perlow's  
17 complication rate was with over tensioning of devices  
18 and what his testimony was regarding over tensioning of  
19 devices, correct?

20 A. That's correct.

21 Q. Did Dr. Adam testify that he found that  
22 the mesh had shrunk?

23 A. I don't believe he used that language.

24 Q. Did he use any language that would be a

1 synonym for shrunk?

2 A. I think his medical records speak  
3 towards a significant compression of the urethra, which  
4 is consistent with shrinkage.

5 Q. The compression of the urethra could  
6 happen as a result of scarring, correct?

7 A. True.

8 Q. It could happen as a result of over  
9 tensioning, correct?

10 A. Theoretically.

11 Q. And you contend that it could happen as  
12 a result of the mesh itself shrinking, correct?

13 A. That's correct.

14 Q. Do you know whether it occurred in this  
15 case due to mesh contracting or scarring?

16 A. I believe it was probably both of those  
17 issues.

18 Q. Do you know -- I assume you don't know  
19 the percentages of each, correct?

20 A. I think it would be difficult to put  
21 forth an opinion on that.

22 Q. It may be all scarring, true?

23 A. Possibly.

24 Q. And does scarring result -- is there

1       scarring with any SUI procedure, surgical procedure?

2               A.       To some degree.

3               Q.       In your Case Specific Opinion Number 2,  
4       you indicate the various causes of dyspareunia that you  
5       rule in and rule out, true?

6               A.       Yes.

7               Q.       I want to ask you, what is your  
8       understanding of when the dyspareunia was worse, after  
9       Dr. Perlow's surgery, after Dr. Adam's surgery, or has  
10      it remained the same?

11              A.       When I interviewed the patient, she  
12      started having dyspareunia about three months after her  
13      2001 surgery.

14              Q.       Has it remained the same or was it  
15      better or worse as a result of the surgery by Dr. Adam?

16              A.       Dr. Adam's surgery was not -- certainly  
17      not curative of the problem, and I'm not convinced it  
18      changed very much with it.

19              Q.       How often were they having sex before --  
20      or after Dr. Perlow's surgery? Was it your  
21      understanding they were unable to or could not?

22              A.       I asked her that question specifically  
23      when I examined her, and she claimed that she used to  
24      be sexually active every day. When I examined -- when

1 I discussed this with her in April -- pardon me -- in  
2 May of 2016, she described being sexually active every  
3 three to four months with pain.

4 Q. Do you know how often she was having it  
5 after Dr. Perlow's surgery before Dr. Adam's surgery?

6 A. Somewhere between three to four times a  
7 year and every day. I don't recall the exact amount.

8 Q. That's a pretty big gap.

9 A. I know it is. I apologize.

10 Q. Was it your understanding after  
11 Dr. Perlow's surgery, she was not sexually active due  
12 to dyspareunia?

13 A. Well, I do recall that, yes.

14 Q. She certainly was not having sex two to  
15 three times a week after Dr. Perlow's surgery, true?

16 A. No, that's true.

17 Q. Because if she was having sex two to  
18 three times a week after Dr. Perlow's surgery, that's  
19 inconsistent with dyspareunia, correct?

20 MR. THOMPSON: Object to the form.

21 THE WITNESS: I'm not sure if I  
22 understand that question.

23 BY MR. GRIFFIN:

24 Q. If she was having sex two to three times

1 a week after Dr. Perlow's surgery, that's inconsistent  
2 with severe dyspareunia, correct?

3 A. Well, it's a little bit of a different  
4 question than you posed before in terms of the use of  
5 the word severe, and I guess I would offer an opinion  
6 that one can still be sexually active and have  
7 dyspareunia. I mean, in other words, in having  
8 dyspareunia doesn't mean I cannot have sex, it just  
9 means one has sex and has discomfort doing so.

10 Q. Right. And she indicated to you she was  
11 having it three to four times a year, correct?

12 A. In 2016, that's what she told me.

13 Q. Which would be severe dyspareunia, as  
14 far as your understanding, true, or a lack of desire, I  
15 guess?

16 A. I think it would be, you know, possibly  
17 consistent with dyspareunia, yes.

18 Q. Okay. Two to three times a week is not  
19 consistent with your experience with patients claiming  
20 dyspareunia, correct?

21 A. Possibly, but not necessarily.

22 Q. Based on your experience, patients who  
23 are having dyspareunia are not having sex two to three  
24 times a week, correct?

1           A.       If it were severe, that would be a  
2     surprise to me.

3           Q.       And she had severe dyspareunia, based  
4     upon what she told you, true?

5           A.       Well, in 2016 she was having severe  
6     dyspareunia and made fairly descriptive comments  
7     regarding what it was like.

8           Q.       Right, and she's told you that she had  
9     had dyspareunia all the way back to Dr. Perlow's  
10    surgery, true?

11          A.       Starting about three months after  
12    Dr. Perlow's surgery, correct.

13          Q.       And it had been severe the entire time,  
14    true?

15          A.       I don't recall her using the word  
16    severe, but suffice it to say, I know that she had had  
17    it ever since that surgery.

18          Q.       Well, the description she gave you would  
19    equal severe. She may not have used that word severe,  
20    but the description she gave you, you would consider  
21    that severe dyspareunia back to the time Dr. Perlow was  
22    treating the patient, true?

23                   MR. THOMPSON: Object to the form.

24                   THE WITNESS: I'm not sure I could

1           answer that question with a great deal of  
2           confidence.

3       BY MR. GRIFFIN:

4           Q.       But your understanding was three to four  
5       times a year, basically, since Dr. Perlow's surgery,  
6       true?

7           A.       No.    When I asked her that question,  
8       that was really more of a question over the last couple  
9       of years, so I didn't ask her specifically, you know,  
10      how often she was having sex, let's say, in 2002 or  
11      2006, so forth.   I know it was an ongoing complaint,  
12      obviously.

13          Q.       Right.

14                 Do you have patients with severe  
15      dyspareunia having sex two and three times a week with  
16      their spouse?

17          A.       Actually, I do.   I'm embarrassed to  
18      bring this up, but it's not vaginal intercourse,  
19      necessarily.

20          Q.       I'm talking about vaginal intercourse,  
21      sexual intercourse.

22          A.       I do not have patients in my practice  
23      with severe dyspareunia that have penetrating  
24      intercourse two to three times a week, unless their



1 husband maybe is -- I mean, there are instances in  
2 which I have patients with severe dyspareunia that  
3 still have sex.

4 Q. Sexual abuse type situations almost,  
5 correct?

6 A. No. It's, you know, more borne out of a  
7 patient's interest in keeping their husband fulfilled,  
8 and, I mean, I have patients that suffer to have sex so  
9 that their husband won't leave them. I mean, this is  
10 the truth.

11 Q. Tell me after Dr. Adam did his surgery,  
12 has there been any evidence of mesh exposure?

13 A. No, sir.

14 Q. Did you see any evidence of mesh  
15 exposure when you examined the patient, whether you  
16 call it exposure or extrusion?

17 A. I did not.

18 Q. You indicate in your report that you  
19 documented tenderness in the right periurethral area?

20 A. Yes.

21 Q. And your report indicates "tenderness  
22 along right periurethral area (? mesh vs. scar)."

23 Did I read that correctly?

24 A. That's correct.

1 Q. Is that because you don't know whether  
2 that is due to a scar or due to mesh?

3 A. I think it may be somewhat similar to a  
4 discourse that you and I had had prior regarding  
5 palpating scar tissue and not being able to determine  
6 if there might be some mesh underneath the scar tissue.  
7 There's no erosion, exposure, extrusion, et cetera, but  
8 there is a palpable thickening of the tissue that might  
9 have mesh underneath it.

10 Q. But you don't know whether there's mesh  
11 at that site, correct?

12 A. Correct.

13 Q. So the tenderness along the right  
14 periurethral area may be caused by the scar itself,  
15 correct?

16 A. You know as an indirect consequence of  
17 her surgeries, yes.

18 Q. And it could be as a result of the  
19 initial scar itself, correct?

20 A. That's hard to answer that question  
21 having not examined her between 2001 and 2005. It's a  
22 possibility.

23 Q. Well, she actually had what she  
24 described as dyspareunia before there was ever exposure

1 of the mesh, correct?

2 A. This is true.

3 Q. Okay. Which would give an indication  
4 that the scar itself from the placement of the mesh may  
5 have been the potential cause for her dyspareunia,  
6 correct?

7 A. Possibly.

8 Q. And that is, of course, a complication  
9 of placement of a TVT or placement of a autologous  
10 fascial graft, correct?

11 A. You are speaking of just the generalized  
12 presence of dyspareunia?

13 Q. The scar, a scar can cause that?

14 A. Any scar can cause that.

15 Q. And I guess when you place an autologous  
16 fascial sling, you have to make an incision in the  
17 vagina as well, correct?

18 A. That's correct.

19 Q. And that scar can lead potentially to  
20 dyspareunia, correct?

21 A. If it's located in the midline, that  
22 would be plausible.

23 Q. Do you ever locate them in the midline?

24 A. On occasion.

1 Q. Do you have patients that you have  
2 implanted autologous fascial slings in who have pain  
3 from the scar, dyspareunia that you attribute to the  
4 scar from the placement of the fascial sling?

5 A. This can happen in uncommon instances,  
6 yes.

7 Q. Do you have patients who that has  
8 happened to?

9 A. One or two, I do.

10 Q. You indicated that you excluded pelvic  
11 floor dysfunction. What did you mean by pelvic floor  
12 dysfunction?

13 A. Pelvic floor dysfunction usually speaks  
14 to issues such as pelvic floor muscle spasm or levator  
15 spasm, as it's sometimes called. This can typically be  
16 diagnosed not only through history taking but through a  
17 physical exam where you can actually document tightness  
18 or spasm of the levator muscles during an examination.

19 Q. Did you do that in your examination?

20 A. I did.

21 Q. Is that documented in your record?

22 A. As part of my examination of the female  
23 genitalia, that's something I typically do. It's not  
24 something that's present, I don't necessarily write no

1 levator spasm or things to that nature.

2 Q. Did you write anything regarding that  
3 test?

4 A. It's just part of my vaginal exam when  
5 I'm doing a bimanual exam to assess for the presence or  
6 absence of that, and, typically, because this is a  
7 template, the template doesn't include absent levator  
8 spasm. It's usually something that's provided if the  
9 finding is there.

10 Q. Did you document that anywhere in this  
11 report, the absence of levator spasm?

12 A. Well, I guess what I didn't document was  
13 the presence of levator spasm, thereby implying that  
14 there was no levator spasm.

15 Q. Well, in your examinations you  
16 specifically make references to things you don't find,  
17 correct?

18 A. I specifically make references using an  
19 electronic health record generated template.

20 Q. Well, you specifically state that you  
21 found tenderness, right?

22 A. Correct.

23 Q. You stated that you found no masses,  
24 atrophy or lesions, correct?

1 A. That's correct.

2 Q. You state you found no urethral  
3 discharge or mass, true?

4 A. In fact, one thing that's very helpful  
5 with electronic health resources is when there is a  
6 specific pertinent, positive finding, it's bolded, as  
7 you can see, relating to the tenderness comment.

8 Q. Is there anything in here that says no  
9 levator spasm?

10 A. There was none found during my exam, so  
11 I didn't provide that, given the fact that it wasn't  
12 part of the template.

13 Q. So it just depends on what's in the  
14 template as to what ends up in the report?

15 A. No, that's not true. What ends up in  
16 the template is generated by the electronic health  
17 resource, but in my examination, if I find something  
18 that's relevant and pertinent, I'll add that.

19 Q. Well, you specifically said that it was  
20 relevant and pertinent in the opinions you were giving  
21 in this case that there was no pelvic floor  
22 dysfunction, correct?

23 A. There is no pelvic floor dysfunction in  
24 any of the medical records, including my IME, that's

1 correct.

2 Q. And you state that --

3 A. In fact -- I'm sorry.

4 Q. Go ahead.

5 A. I was just going to say Dr. Adam made  
6 mention of the fact that in his examination in 2005,  
7 her levator ani were normal.

8 Q. And you say there's an absence of  
9 documented tenderness to the pelvic floor musculature  
10 by multiple consultants, correct?

11 A. That's correct.

12 Q. Who are these multiple consultants?

13 A. Dr. Adam, Dr. Sward.

14 Q. Dr. Adam, 2005?

15 A. Yeah. Dr. Sward in 2004. Myself.

16 There's no mention in Dr. Osterloh, if I'm saying her  
17 name right, in her findings of such.

18 Q. She doesn't do a pelvic exam, does she?

19 A. This is true.

20 Q. Has a single pelvic exam been done on  
21 this patient since 2005 until the time you saw her in  
22 2016?

23 A. I have no evidence of such.

24 Q. So as far as you can tell from your

1 review of the records, for 11 years she did not have a  
2 single vaginal examination?

3 A. Not that I have seen, no.

4 Q. Did you see any complaints to any  
5 physicians from 2005 to the time you saw her  
6 complaining about dyspareunia?

7 A. I did not.

8 Q. Did you find any complaints of  
9 dyspareunia that occurred before she -- from 2005 until  
10 after she filed this lawsuit?

11 A. I did not.

12 Q. Does she suffer from incontinence  
13 currently?

14 A. Not currently, no.

15 Q. Did she have incontinence before the  
16 procedure performed by Dr. Perlow?

17 A. Yes, sir, she did.

18 Q. So would it be your conclusion that the  
19 TVT has corrected her incontinence?

20 A. No.

21 Q. And that's because?

22 A. Well, she's required multiple surgeries  
23 since her TVT to resolve her incontinence.

24 Q. What are the multiple surgeries?



1           A.       Well, firstly, she had collagen  
2   injections following her SUI surgery, the TVT-O  
3   placement.

4           Q.       Those had a temporary effect, correct?

5           A.       That had a temporary benefit.

6           Q.       Okay. That's not surgery, is it? I  
7   guess it depends on your definition.

8           A.       Well, it depends how one defines it.  
9   It's a minor surgery or a minor procedure, if you will.

10          Q.       Okay.

11          A.       Sometimes those are done in the office,  
12   sometimes those are done in a hospital setting, so I  
13   think it's hard to say whether you call it surgery or  
14   otherwise.

15          Q.       The only other true surgery was the  
16   excision of the mesh, correct?

17          A.       Yeah, and along those lines, when she  
18   originally presented to Dr. Adam in February of 2005,  
19   her urinary incontinence was ongoing.

20          Q.       But by the time you see her, there is no  
21   urinary incontinence?

22          A.       This is true.

23          Q.       Did it self-heal?

24          A.       Following Dr. Adam's surgery, her

1 incontinence resolved. When she last saw Dr. Adam,  
2 July 14, 2005, a little over four months  
3 postoperatively, she was still leaking occasionally.  
4 By the time I saw her, she was no longer having  
5 incontinence.

6 Q. So Dr. Adam removed a portion of the  
7 sling?

8 A. That's correct.

9 Q. And by removing a portion of the sling,  
10 the patient -- it resolved the patient's incontinence?

11 A. Ultimately, that surgery proved to be  
12 successful in that regard, yes.

13 Q. But the TVT, a portion of it remains in  
14 place, correct?

15 A. That's correct.

16 Q. So the remaining portion is what is I  
17 guess taking care of her incontinence?

18 A. Not exactly, no.

19 Q. What is?

20 A. Well, one of the premises around which  
21 mesh-based slings work is their ability to create an  
22 inflammatory response and scar tissue. One of the  
23 reasons you can see mesh-related complications is in  
24 part related to the inflammation and scar tissue that

1 results.

2                   If you can imagine, at least when I  
3 examined Ms. Bailey, what she had was one piece of mesh  
4 on the right side, one piece of mesh on the left side  
5 and then a scar bridge between those two pieces of  
6 mesh. So really her continent mechanism is not only in  
7 part related to the mesh but the very inflammatory  
8 response and scar tissue formation that one expects  
9 from the mesh. That's one of the reasons you don't  
10 have to suture mesh in place. It self-affixes by  
11 virtue of the inflammatory response it creates.

12               Q.       So the effect of the TVT in causing scar  
13 tissue is what has solved her incontinence, would that  
14 be a fair way to say it?

15                   MR. THOMPSON: Object to the form.

16                   THE WITNESS: I think it's a combination  
17 of both. In other words, in instances where  
18 you removed more of the mesh, the scar tissue  
19 doesn't necessarily provide all of the support  
20 needed to provide continence. In this  
21 instance, obviously, whether it's scar tissue  
22 or the actual mesh itself, it succeeded in  
23 doing so.

24 BY MR. GRIFFIN:

1 Q. So you believe that there's a  
2 combination of the mesh and the scar tissue that was  
3 caused by the implantation of the mesh that is -- has  
4 cured her incontinence; would that be a fair way to say  
5 it?

6 MR. THOMPSON: Object to the form.

7 THE WITNESS: I would add to that and  
8 say as well as the additional surgery scarring  
9 that has done that, yes.

10 BY MR. GRIFFIN:

11 Q. So the dyspareunia which she currently  
12 has could be caused by the incisional scar alone,  
13 correct?

14 A. Not correct. Not based on my evaluation  
15 and examination where -- well, couple of points to  
16 make. First off, the majority of her tenderness that  
17 she described as being what she felt when she had  
18 dyspareunia is on the right side of her vaginal space  
19 so that periurethral space, number one.

20 Q. Was there an incision in that area where  
21 the mesh was removed?

22 A. Not necessarily, but possibly. I think  
23 to really formulate a better opinion on that, I really  
24 have to relook at Dr. Adam's operative note to make a

1 comment to that effect, and the reason I say that is  
2 because typically in the setting of a partial mesh  
3 excision, one will typically make a midline incision  
4 and then access the eroded mesh from that midline  
5 incision by dissecting underneath the vaginal space to  
6 access the mesh.

7 And, as I sit here today, I'm not  
8 specifically recalling if Dr. Adam made that approach  
9 towards removing the mesh, in other words, a midline  
10 incision, or whether he incised transversely, if you  
11 will, under the mesh to deliver it, in which case your  
12 question and your theory would be plausible.

13 Q. Did you indicate that the patient  
14 currently has incomplete bladder emptying?

15 A. My comment made was that she has to  
16 strain to urinate.

17 Q. So that's a voiding dysfunction, in  
18 essence, correct?

19 A. Yes, sir.

20 Q. Did you do any post void residual  
21 testing on her?

22 A. I did not.

23 Q. And what would you be looking for in  
24 that kind of testing?

1           A.       Well, there are two ways to assess for  
2   incomplete bladder emptying from an objective  
3   standpoint.   Certainly one of the best is to scan the  
4   bladder after urination and assess their post void  
5   residual.   Oftentimes you can get a sense of their  
6   emptying ability on the basis of a physical  
7   examination, where you palpate over the suprapubic area  
8   in the location of the bladder to sense, number one, if  
9   you can palpate their bladder and/or, number two, if  
10   they feel a desire to urinate upon that palpation.

11           Q.       Did you do that?

12           A.       I did.

13           Q.       What did you find?

14           A.       I didn't clinically suspect her of  
15   having incomplete bladder emptying based on my physical  
16   examination in the absence of a bladder scan.

17           Q.       Was that inconsistent or consistent with  
18   her continued voiding dysfunction?

19           A.       Well, I think that you have to take into  
20   account that the diagnosis of incomplete bladder  
21   emptying can be a subjective one as well as an  
22   objective one.   Certainly, the fact that she is  
23   straining to void suggests that she has some sort of  
24   bladder outlet obstruction.   Whether that's manifesting

1 with an actual objective finding of elevated post void  
2 residuals or a true objective incomplete bladder  
3 emptying doesn't necessarily mean a patient can't have  
4 that feeling.

5 Q. When was the last post void residuals  
6 done on this patient?

7 A. From my recollection, July 14th, 2005.

8 Q. And what were the results of that?

9 A. It was 10 CCs.

10 Q. That's pretty small, isn't it?

11 A. Yes.

12 Q. That would not support incomplete  
13 bladder emptying, correct, objectively?

14 A. I would agree with that.

15 Q. So that would be inconsistent with  
16 voiding dysfunction?

17 A. Well, I think the fact that someone is  
18 complaining about having that, yet doesn't have that,  
19 to me is part of the syndrome of voiding dysfunction.

20 Q. She has complained specifically of  
21 incomplete bladder emptying, correct?

22 A. Having that feeling, yes.

23 Q. All objective testing that's been done  
24 by you and by Dr. Adam in 2005 doesn't support that,

1 true?

2 A. That's correct.

3 MR. GRIFFIN: Take a break for a minute.

4 (Brief recess taken at 12:03 p.m.)

5 (Deposition resumes at 12:09 p.m.)

6 BY MR. GRIFFIN:

7 Q. Dr. Walmsley, you stated that you felt  
8 it was an induration or was it just tenderness in the  
9 right periurethral area?

10 A. Well, it was both based on the comment  
11 made following that question, mesh versus scar.

12 Q. Okay. Is it your understanding where  
13 you felt that tenderness, that was where the mesh was  
14 excised?

15 A. Possibly, yes.

16 Q. So necessarily an incision would have  
17 been made where the mesh was excised, correct?

18 A. Well, as I alluded to before, sometimes  
19 the surgical technique involves making a midline  
20 incision and then tracking underneath the vaginal  
21 lining to the area of the mesh erosion. Other  
22 instances involve making incision adjacent to the mesh  
23 erosion. Suffice it to say, the area of her mesh  
24 erosion and subsequent removal was certainly in the



1 area where my examination would indicate that that  
2 surgery was done.

3 Q. And that one of the ways you would  
4 remove that mesh is to make your incision just proximal  
5 to the area where the mesh was exposed, correct?

6 A. Yeah, and that's my understanding as to  
7 what Dr. Adam did.

8 Q. Okay. And that would not be midline  
9 based upon your findings in 2016, correct?

10 A. Neither based on my findings or the  
11 location of the actual erosion based on Dr. Adam's  
12 records.

13 Q. So there was an actual incision and scar  
14 tissue in that area probably from the surgery itself,  
15 correct?

16 A. The incision I think was proximal to  
17 that area, but close to it.

18 Q. And your point in your examination is  
19 that that tender area may be the scarring itself from  
20 the incision or scarring from mesh, correct?

21 A. No, that was not my insinuation from the  
22 exam. My insinuation from the exam was that that  
23 tenderness could be relating to the mesh itself or to  
24 scar tissue. I wasn't attributing it to the incision

1 per se.

2 Q. Well, the incision created scar tissue  
3 itself, correct?

4 A. Yes, to some degree this is true, yes.

5 Q. And that scar tissue could be causing  
6 the tenderness and dyspareunia, correct?

7 A. I guess for the purposes of specificity,  
8 are you talking about the incision from Dr. Adam's  
9 procedure or the incision from Dr. Perlow's procedure?

10 Q. Well, it could be the incision from  
11 Dr. Adam's procedure, correct?

12 A. Well, the only reason I have to take  
13 issue with that is because when Dr. Adam examined her  
14 prior to his surgery, he was able to elicit tenderness  
15 in that area prior to his own incision.

16 Q. Right.

17 There was mesh exposure at that time,  
18 true, when Dr. Adam saw the patient?

19 A. Yes, sir.

20 Q. And there was tenderness in the area of  
21 the mesh exposure, true?

22 A. True.

23 Q. And Dr. Adam -- and up until that point  
24 in time, the patient was having sex two to three times

1 a week, correct?

2 A. That is true.

3 Q. So up until the time Dr. Adam operated  
4 on this patient, she was having sex with her husband  
5 two to three times a week, true?

6 A. Yes.

7 Q. And then after Dr. Adam operated on the  
8 patient, how often was she able to have sex?

9 A. To my mind, less frequently than that.

10 Q. And is it your understanding from  
11 reading the fact witness depositions that everything  
12 went downhill as far as their sex lives after  
13 Dr. Adam's procedure?

14 A. I wouldn't read it as such, no.

15 Q. How did you read it?

16 A. Well, I felt like the problem started  
17 after her sling surgery was done and were not  
18 ameliorated by Dr. Adam's procedure.

19 Q. So you did not have the understanding  
20 that everything went downhill after Dr. Adam's  
21 procedure as far as their sex life?

22 A. I think things worsened after that  
23 procedure, but they weren't in tip-top shape going into  
24 that procedure either.

1 Q. Well, they were in pretty good shape if  
2 she was having sex two to three times a week, weren't  
3 they?

4 A. Well, once again, I think you have to  
5 qualify the enjoyment of that process. I mean, for  
6 better or for worse, as my understanding goes, she was  
7 having discomfort during sex but was doing so  
8 regardless.

9 Q. Where did you read that?

10 A. This is based on my discussions with  
11 her.

12 Q. And that's what she told you, she was  
13 having sex despite being in pain?

14 A. She used words -- both her and her  
15 husband expressing feelings of guilt to the point that  
16 he felt guilty about doing it now because of the fact  
17 that he knew how uncomfortable it was for her, but that  
18 flavor was insinuated to their sex life after the TVT-O  
19 sling was placed as well, that it wasn't necessarily a  
20 comfortable act for her.

21 Q. Did you read Houston Bailey's  
22 deposition, her husband's deposition?

23 A. I did not.

24 Q. So when you offered these opinions

1 regarding when the dyspareunia was worse, when the  
2 dyspareunia was better, you had not had the opportunity  
3 to review Houston Bailey's deposition?

4 A. I hadn't read his.

5 Q. You had not?

6 A. I had not read that deposition.

7 Q. As I understand it, if a patient has  
8 exposure of the mesh into the vagina, her partner may  
9 feel a scratching sensation or a prickling sensation,  
10 correct?

11 A. That's described often, yes.

12 Q. Okay. When you saw the patient in 2015,  
13 did they have exposure of the mesh?

14 A. It was in 2016.

15 Q. 2016, there was no exposure of mesh?

16 A. I did not appreciate such.

17 Q. You did not feel a slicing or a cutting  
18 of your finger or anything of that sort when you  
19 conducted your manual examination, correct?

20 A. I just felt palpable scar.

21 Q. There was nothing that would be causing  
22 a scratching or cutting or scraping of the penis,  
23 correct?

24 A. Possibly scar tissue, but, certainly, I

1 wouldn't attribute that to a mesh exposure phenomenon.

2 Q. And you didn't feel that type of  
3 scratching sensation when you conducted your  
4 examination of the patient manually, correct?

5 A. Well, using my gloved finger I did not,  
6 no.

7 Q. Are you currently using midurethral  
8 sling procedures?

9 A. I am.

10 Q. Do you read the IFU before you do every  
11 midurethral sling procedure?

12 A. I try to stay up-to-date with the IFUs,  
13 yes.

14 Q. Do you read the IFU every time you do a  
15 midurethral sling procedure?

16 A. I tend to look at the IFUs about once a  
17 year, so if you're saying before each individual  
18 procedure do I pull out the IFU and look at it, the  
19 answer to that would be no. Sometimes if there's  
20 turnover time, you've got nothing better to do, you  
21 might take a glimpse at it and just make sure nothing  
22 has really changed.

23 Q. And in doing your informed consent with  
24 the patient, you do not rely only on the IFU, do you?

1           A.       I use it as part of my informed consent,  
2   that's true.

3           Q.       Right. And what are the other things  
4   you use as part of your informed consent?

5           A.       My training, as it relates to  
6   transvaginal mesh, some of the workshops I have  
7   attended.

8           Q.       What you've read?

9           A.       To some degree, yes.

10          Q.       What you'd experienced in your own  
11   practice?

12          A.       This is true.

13          Q.       I don't know if workshops included this,  
14   but whatever seminars you may have attended or cadaver  
15   labs, things like that?

16          A.       A lot of the workshops had didactic  
17   sessions, not only talking about the history of mesh,  
18   but the design of the mesh and what perhaps made it  
19   different from other products and so forth.

20          Q.       And all of that information goes into  
21   the informed consent that you give a patient, correct?

22          A.       Would be very helpful.

23          Q.       You don't simply rely on reading the IFU  
24   to the patient, do you?

1           A.       I never read the IFU to the patient per  
2   se, but I do use it as a framework or a foundation, if  
3   you will, in terms of counseling a patient.

4           Q.       You don't have the IFU in your hands  
5   when you counsel a patient, do you?

6           A.       I do not. That might make a patient a  
7   little nervous.

8           Q.       Do you show the patient the mesh?

9           A.       In certain instances I have, but not  
10   all.

11          Q.       And when you give the informed consent,  
12   you counsel a patient on what your personal experience  
13   has been, correct?

14          A.       I do.

15          Q.       And so a physician cannot simply rely on  
16   the IFU alone, they should also tell the patient  
17   information they know of that's based on their  
18   experience, their learning, reading, things of those  
19   sorts, correct?

20                   MR. THOMPSON: Object to the form.

21                   THE WITNESS: I think that can be very  
22                   helpful in facilitating a proper informed  
23                   consent.

24   BY MR. GRIFFIN:



1 Q. Are polypropylene mesh slings like the  
2 TVT the standard of care for surgical treatment of SUI?

3 A. Not necessarily.

4 Q. Is it within the standard of care for a  
5 physician to use a TVT for the surgical treatment of an  
6 SUI?

7 A. I believe with proper informed consent,  
8 this is true.

9 Q. Was it within the standard of care for  
10 Dr. Perlow to recommend the polypropylene mesh sling  
11 like the TVT for Ms. Bailey?

12 MR. THOMPSON: Object to the form.

13 THE WITNESS: Based on the available  
14 fund of knowledge available to him at that  
15 time, I do believe it was the standard of care.

16 BY MR. GRIFFIN:

17 Q. And you've not had the opportunity to  
18 review his knowledge, so you don't know what he had in  
19 his head to tell her, correct?

20 A. The only fund of knowledge that I would  
21 have known he would have possibly been in receipt of,  
22 if you will, was the IFU at that time.

23 Q. And as you've already pointed out, a  
24 physician shouldn't rely on just the IFU, they should

1 also use the fund of knowledge that they obtain from  
2 other sources in providing informed consent, correct?

3 A. To some extent, this is true.

4 Q. I mean, that is the standard of care,  
5 isn't it?

6 A. Well, the issue, once again, based on  
7 what I determine to be the standard of care is that the  
8 IFU is the framework, it's the foundation, it's the  
9 foundation on which key opinion leaders, literature and  
10 other things that formulate an informed consent depend  
11 upon.

12 Q. So as long as appropriate informed  
13 consent is given, you're of the opinion that the  
14 midurethral polypropylene slings are a safe and  
15 effective form of SUI treatment, correct?

16 MR. THOMPSON: Object to the form.

17 THE WITNESS: Well, I wouldn't offer  
18 that opinion. I would offer the opinion that  
19 it's effective. I think one has to refine what  
20 one -- the term "safe." The fact that I'm  
21 still doing it certainly would infer that I  
22 believe it's appropriate for a subset of  
23 patients with proper informed consent who  
24 understand the ramifications, both good and

1 bad, to utilizing transvaginal mesh.

2 BY MR. GRIFFIN:

3 Q. Is it true that after an appropriate  
4 informed consent has been given for some of your  
5 patients, you believe it is a safer and more effective  
6 form of stress urinary incontinence treatment than  
7 other treatments?

8 A. For certain patients, this is true.

9 Q. And do you agree that polypropylene mesh  
10 midurethral slings are the standard of care for the  
11 surgical treatment of SUI?

12 A. I think they're one of the standards of  
13 care that we rely upon in our armamentarium to treat  
14 the condition.

15 Q. So one of the standards of care?

16 A. I would opine that for select patients  
17 it would be an appropriate procedure.

18 Q. You indicated one of the alternative  
19 procedures was the autologous sling?

20 A. Yes, sir.

21 Q. Does that require hospitalization?

22 A. It does.

23 Q. Does that require overnight stay?

24 A. Usually it does.

1 Q. Does the mesh TVT type procedures have a  
2 reduced hospitalization as compared to the autologous  
3 sling?

4 A. Insofar as hospital stay, this is true.

5 Q. And does it have reduced surgical pain,  
6 the TVT type midurethral slings?

7 A. Sometimes it does, yes.

8 Q. And it's your understanding that  
9 mesh-related complications can occur following  
10 polypropylene sling placement, but the rate of  
11 complications is acceptably low?

12 A. Well, I would disagree with that.

13 Q. From a quantitative point, do you  
14 believe it's acceptably low?

15 A. From a quantitative point of view, it's  
16 relatively low.

17 Q. And if it were too high, you wouldn't be  
18 recommending it, correct?

19 A. Well, that's exactly true.

20 MR. THOMPSON: Mr. Griffin, I hate to  
21 interrupt, because I do want to let you go  
22 forward, but are you making reference to an  
23 earlier deposition of Dr. Walmsley?

24 MR. GRIFFIN: Yes.

1 MR. THOMPSON: Well, is this the  
2 deposition that was on Friday?

3 MR. GRIFFIN: No.

4 MR. THOMPSON: Okay. All right, thanks.

5 MR. GRIFFIN: I wasn't here Friday,  
6 fortunately neither were you.

7 MR. THOMPSON: Then that's fair game.  
8 Thank you.

9 MR. GRIFFIN: No, I'm not repeating what  
10 was done on Friday, because I have no idea what  
11 was done on Friday because I wasn't here.

12 BY MR. GRIFFIN:

13 Q. What type of device do you currently use  
14 that is like the TVT?

15 A. Currently I use a Coloplast Aris sling.

16 Q. And what is the difference between that  
17 and the TVT type?

18 A. The mesh is somewhat different. It's  
19 somewhat less -- it has somewhat less elasticity, if  
20 you will.

21 Q. The Coloplast has less elasticity?

22 A. It doesn't stretch as readily as the TVT  
23 sling.

24 Q. More rigid?

1           A.       I don't know if I would offer the term  
2   "rigid." It just doesn't stretch as readily.

3           Q.       So was it appropriate for Dr. Perlow to  
4   recommend the TVT procedure for Ms. Bailey's  
5   incontinence in this case?

6                   MR. THOMPSON: Object.

7                   THE WITNESS: Based on his fund of  
8   knowledge, I agree.

9   BY MR. GRIFFIN:

10          Q.       And to this date, 2016, that's still one  
11   of the options you offer your patients, correct, the  
12   TVT midurethral sling type procedures?

13          A.       In select patients with proper informed  
14   consent, this is true.

15                   MR. GRIFFIN: I'll reserve the rest of  
16   my time.

17   BY MR. THOMPSON:

18          Q.       Doctor, earlier in your testimony you  
19   had talked about that autologous grafts had risk of  
20   dyspareunia and other complications the same as slings  
21   did.

22                   Do you recall that portion of the  
23   testimony?

24          A.       If I had said it that way, I stand

1 corrected, but I do recall us discussing the fact that  
2 autologous fascial slings do run the risk of  
3 dyspareunia, yes.

4 Q. In terms of assessing the risk and  
5 efficacy of the various modes of treatment, is it  
6 important to know and understand the frequency of  
7 complications as between the two or between the  
8 multiple procedures?

9 MR. GRIFFIN: Object to form, leading.

10 THE WITNESS: Yeah, I think that's very  
11 helpful.

12 BY MR. THOMPSON:

13 Q. Is it a part of informed consent to  
14 advise patients as to the frequency of complications?

15 A. Yes.

16 Q. Is it a part of informed consent that  
17 you advise patients of the severity of those  
18 complications?

19 MR. GRIFFIN: Object to form.

20 THE WITNESS: Yes.

21 BY MR. THOMPSON:

22 Q. Is it part of informed consent that you  
23 advise patients as to what complications may be  
24 permanent as opposed to what complications may be

1 transient?

2 A. Yes.

3 Q. And is it a part of informed consent to  
4 advise patients as to the ease or the impossibility of  
5 correcting complications?

6 A. Yes.

7 Q. Okay. Doctor, you've had an opportunity  
8 to hear some additional information and to review it  
9 today, and also you've heard that there may be  
10 depositions that you have not yet considered.

11 Do any of these additional facts or any  
12 additional information cause you to retract the  
13 opinions that you've expressed in your report?

14 A. No.

15 Q. Doctor, I note in your report, you  
16 signed the report, do the opinions that you've  
17 expressed in the report and the opinions that you've  
18 expressed -- that you've been examined upon today, do  
19 you hold these opinions to a reasonable degree of  
20 medical certainty?

21 A. I do.

22 Q. At one point in your deposition, you had  
23 indicated that you couldn't differentiate between the  
24 extent of the mesh itself and the scarring as causing



1 Ms. Bailey's symptoms.

2 Do you recall that?

3 A. I do.

4 Q. In any event, even if you're not able to  
5 ascertain the exact amount or proportion, can you say  
6 that the mesh participated in the symptoms that  
7 Ms. Bailey suffered and suffers today?

8 MR. GRIFFIN: Object to form.

9 THE WITNESS: Yes, I can.

10 BY MR. THOMPSON:

11 Q. Can you say that the mesh was a  
12 substantial contributing factor in the symptoms that  
13 Ms. Bailey has suffered and suffers from today?

14 A. Yes.

15 MR. THOMPSON: Thank you, Doctor.

16 That's all I have.

17 BY MR. GRIFFIN:

18 Q. And would you agree that the scarring  
19 was a substantial contributing factor to the symptoms  
20 Ms. Bailey has suffered and suffers from today?

21 A. Are you speaking about --

22 Q. Incisional scarring.

23 A. Oh, incisional?

24 Q. Yes.

1           A.       Not so much as the mesh-induced  
2   scarring, I wouldn't offer that opinion.

3           Q.       But you don't know at this point, do  
4   you?

5           A.       Well, what I know is that the incision  
6   would have been -- not have been there had the mesh not  
7   have been there.

8           Q.       The mesh was taken out because of  
9   dyspareunia; is that correct?

10          A.       Not completely.

11          Q.       It was also because of exposure,  
12   correct?

13          A.       That was part of it, yes.

14          Q.       And once the exposed mesh was trimmed,  
15   there has been no additional exposure, to your  
16   knowledge, correct?

17          A.       No.

18          Q.       But the patient continues to complain of  
19   dyspareunia at least as of the time you saw her?

20          A.       Correct.

21          Q.       But we have no medical -- or complaints  
22   to physicians for 11 years or so, correct, of  
23   dyspareunia?

24          A.       She's had no evidence in the medical

1 records since 2006.

2 Q. 2005?

3 A. Was it 2005? Correct, July 14, 2005, I  
4 haven't seen any medical records of any kind since that  
5 time.

6 Q. That evidence any complaints of  
7 dyspareunia, correct?

8 A. That's correct.

9 Q. But that was one of the primary  
10 complaints she made to you, true?

11 A. She had several complaints, that was one  
12 of them, yes.

13 Q. It was one of the primary ones, wasn't  
14 it?

15 A. Well, she talked also about her voiding  
16 dysfunction.

17 Q. Were those the two issues?

18 A. That's correct.

19 Q. Okay. And when these patients come to  
20 you for examination, the ones where you've been  
21 retained as an expert, do you explain to them that  
22 you're examining them on behalf of their -- their  
23 lawyers hired you to examine them?

24 A. I do.

1 MR. THOMPSON: Object to the form.

2 BY MR. GRIFFIN:

3 Q. And you're working with their lawyer on  
4 their case and that they should give you a full  
5 history?

6 A. I don't really get too involved with  
7 discussing with them the role of attorneys in this. I  
8 really try to keep it between patient and myself. I  
9 want to keep it as independent as possible, if you  
10 will.

11 Q. But you explain to them that you're not  
12 a treating physician, correct?

13 A. What I do is I explain to them that  
14 they're coming here as part of an independent medical  
15 exam, and I want to gather information about them and  
16 examine them, and that's essentially the gist of it.

17 Q. But you explain to them your  
18 involvement, though, that you've been retained by their  
19 lawyer, right?

20 A. I mean, I usually don't, mostly because  
21 I feel like they probably know that already.

22 Q. Probably get that, right?

23 A. Yeah. Once again, I mean, I really try  
24 to keep it as objective and dispassionate, if you will,

1 as possible.

2 Q. Based upon your review of these medical  
3 records and your discussions with Ms. Bailey, when did  
4 she become aware that she had a problem with the mesh?

5 A. Well, it really wasn't until the time  
6 that she saw Dr. Adam.

7 Q. So that would have been when?

8 A. February 2nd, 2005.

9 Q. And at that point is it your  
10 understanding that she became aware that there was a  
11 problem with the mesh?

12 A. Well, I'm not sure if she really  
13 understood the nature of the mesh problem. I mean,  
14 Dr. Adam brought to her attention that there was mesh  
15 exposed and that obviously there was tenderness in the  
16 context of finding that.

17 Q. And he actually told her he was going to  
18 operate to remove some of the mesh, correct?

19 A. He suggested that he do that. I think  
20 this is after the urodynamics test is -- well, a couple  
21 of months after that is when the operation took place.

22 Q. Right. So at least as of that point in  
23 time, she was made aware that there was a problem with  
24 the mesh and that a portion of it would need to be

1 removed?

2 A. Correct.

3 Q. And that time period is 2005?

4 A. That's correct.

5 Q. You indicated one of the alternative  
6 treatments was collagen injections; is that true?

7 A. Yes.

8 Q. And did she benefit from those for any  
9 length of time?

10 A. Well, after the sling she did have a  
11 series of collagen injections that were helpful for a  
12 couple of months. I think I said two to three months  
13 in my IME.

14 Q. Apparently not a permanent solution to  
15 her problems?

16 A. Not a permanent solution to her  
17 problems, this is true.

18 Q. Did you find a cystocele or a rectocele  
19 when you examined the patient?

20 A. I did not.

21 Q. Did Dr. Adam document that he saw both  
22 or one or the other?

23 A. He described findings of mild prolapse,  
24 mild rectocele and cystocele.

1 Q. So there was a finding of pelvic  
2 prolapse, correct?

3 A. Certainly not one of clinical relevance,  
4 but he makes documentation of such.

5 Q. But as of the time you saw the patient,  
6 there was no evidence of even mild pelvic prolapse?

7 A. I didn't find anything, no.

8 Q. What happens anatomically for it to go  
9 away between the examinations?

10 A. Well, I think to some degree, there is  
11 perception on part of the eye of the beholder, if you  
12 will. I think when it comes to a mild prolapse, that  
13 mild might be so mild as to be perhaps imperceptible or  
14 not felt to be clinically relevant, and I certainly  
15 think in Dr. Adam's instance, if the prolapse were one  
16 that were clinically relevant, he probably would have  
17 repaired them, yet he did not.

18 All I can tell you is that in my exam I  
19 did not find any significant findings of pelvic  
20 prolapse.

21 Q. So when you say eye of the beholder,  
22 this may have been something Dr. Adam saw that you  
23 didn't appreciate; is that what you're saying?

24 A. I mean, I can't speak for the nature in

1     which Dr. Adam does his pelvic exams. You know, when I  
2     do my pelvic exams, I place patients into what's called  
3     a frog leg position and have them strain or bear down.  
4     It's possible that he might have examined the patient  
5     standing. He may have examined the patient in  
6     stirrups. He may have had her bear down a little  
7     harder to generate some sort of prolapse. In my  
8     instance, with the way that I do my exam, I didn't come  
9     across any significant findings of prolapse.

10           Q.       What is Stage 2 AP/PP pelvic organ  
11     prolapse?

12           A.       That you may be referring to what's  
13     called the POP-Q description of prolapse. Stage 2 is  
14     related finding some mild prolapse.

15           Q.       Is that what he found?

16           A.       I believe that's what he documented in  
17     his medical records.

18           Q.       What's Stage 1?

19           A.       Stage 1 is a different degree of  
20     prolapse. That's probably less.

21           Q.       Is that less?

22           A.       Yes.

23           Q.       So would that be mild also?

24           A.       Well, once again, I mean mild, moderate,



1     severe, what I rely upon, besides my own IME, is does  
2     the functional or anatomical findings correlate to any  
3     significant symptoms or treatment thereof, and,  
4     certainly, in his instance, whether it was Grade 1, 2,  
5     3 or 4, he didn't see it necessary to repair it or  
6     address it in his surgery.

7             Q.       So your point is that the pelvic  
8     prolapse that he saw didn't -- it doesn't go way, it  
9     just may not have been appreciated by you; is that  
10    right?

11            MR. THOMPSON:   Object to form.

12            THE WITNESS:    I'd be hard pressed to  
13     imagine it going away.   There is a certain  
14     subjectivity to physical examinations,  
15     especially with pelvic exams, that relate to a  
16     variety of different conditions, one being the  
17     positioning of the patient, the next being the  
18     degree to which a patient strains or what we  
19     call Valsalvas to generate a dropping.

20            What I can tell you is that in my exam  
21     asking this patient to bear down, lying supine  
22     in a frog leg position, I did not appreciate  
23     any significant pelvic prolapse.

24    BY MR. GRIFFIN:

1           Q.       You described that sometimes during your  
2       examinations, you find a, quote, induration; is that  
3       right?

4           A.       That's correct.

5           Q.       And that's the wording you used in your  
6       opinion letter?

7           A.       That's correct.

8           Q.       And induration implies, what, a  
9       hardening of the tissue, in essence?

10          A.       Perhaps a combination of thickening and  
11       hardening, yes, what one might expect to see, for  
12       example, with scar tissue or inflamed tissue.

13          Q.       And I was looking at your -- I guess  
14       it's called an encounter summary, your notes of your  
15       examination of Ms. Bailey.

16          A.       Yes.

17          Q.       And did you use that word induration or  
18       thickening of scar tissue?

19          A.       I used scar in place of induration.

20          Q.       That's in the parentheses with the  
21       question mark, correct?

22          A.       That's correct.

23          Q.       Anywhere else, or do you just say  
24       tenderness?

1           A.       Tenderness is one of the findings that I  
2   encountered during the exam, along with this area of  
3   scar and/or induration.

4                   The reason I placed mesh versus scar in  
5   parentheses is because to the point of our discussions  
6   beforehand, it's unclear to me as to whether or not  
7   there is actual mesh underneath that scar tissue  
8   underneath that area of induration that is tender.

9           Q.       Just so I'm clear, you do not use the  
10   term induration in your actual examination of this  
11   patient, true?

12           A.       I did not use the word induration in my  
13   verbiage here. If it was there and you were to ask me  
14   if that was true, I'd say, yes, this is true.

15           Q.       In your experience, is dyspareunia a  
16   frequent complaint you encounter in patients?

17           A.       I see a reasonable percentage of my  
18   female patients, yes.

19           Q.       What percentage of your female patients  
20   have dyspareunia?

21           A.       That's a tough question to answer,  
22   because in a lot of instances when I'm seeing a  
23   patient, if, for example, they're coming to me with  
24   complaints of hematuria, I'm not always asking about

1 dyspareunia. So to some degree it depends on how  
2 interested I am in sussing out that condition, but if I  
3 had to give you a ballpark estimate, I would say maybe  
4 10% of my patients.

5 Q. So of the patients you ask, about 10% or  
6 is it more than 10%?

7 A. Well, it might be more than 10%, only  
8 because I'm not necessarily asking that question if I'm  
9 seeing a patient, for example, who has a kidney stone,  
10 I'm not going to start talking about sex, necessarily.

11 Q. I get what you're saying. It may just  
12 be 10% because you're not asking a certain portion of  
13 the patients, correct?

14 A. Correct, yes.

15 Q. But of those patients you ask and  
16 discuss dyspareunia, it's probably a higher percentage  
17 than 10%, true?

18 A. It may very well be.

19 Q. And it may be more along the lines of 20  
20 plus percent, correct, of your patients that you talk  
21 to about dyspareunia?

22 MR. THOMPSON: Object to form.

23 THE WITNESS: That's a bit of a robust  
24 number. I don't know if I'd necessarily agree

1 with that.

2 BY MR. GRIFFIN:

3 Q. So somewhere between 10 and 20%?

4 A. I'm thinking between 10 and 15%, but,  
5 once again, it's a little bit of a conjecture. I don't  
6 ask every patient about that complaint.

7 Q. Do all those patients have transvaginal  
8 mesh, midurethral slings, anything of that sort?

9 A. Some do, some don't.

10 MR. GRIFFIN: No further questions.

11 (Witness excused.)

12 (Deposition concluded at 12:50 p.m.)

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C E R T I F I C A T I O N

I, MARGARET M. REIHL, a Registered Professional Reporter, Certified Realtime Reporter, Certified Shorthand Reporter, Certified LiveNote Reporter and Notary Public, do hereby certify that the foregoing is a true and accurate transcript of the testimony as taken stenographically by and before me at the time, place, and on the date hereinbefore set forth.

I DO FURTHER CERTIFY that I am neither a relative nor employee nor attorney nor counsel of any of the parties to this action, and that I am neither a relative nor employee of such attorney or counsel, and that I am not financially interested in the action.

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Margaret M. Reihl, RPR, CRR, CLR

CSR #XI01497 Notary Public

Konstantin Walmsley, M.D.

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Konstantin Walmsley, M.D.

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ACKNOWLEDGMENT OF DEPONENT

I, KONSTANTIN WALMSLEY, M.D., do hereby  
certify that I have read the foregoing pages,  
and that the same is a correct transcription of  
the answers given by me to the questions  
therein propounded, except for the corrections  
or changes in form or substance, if any, noted  
in the attached Errata Sheet.

---

KONSTANTIN WALMSLEY, M.D.                      DATE

Subscribed and sworn to before me this

\_\_\_\_\_ day of \_\_\_\_\_, 2016.

My commission expires:\_\_\_\_\_

---

Notary Public